IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
John F. SHANLEY *et al.*	Art Unit: 3738
Application No.: **10/729,631**	Examiner: Blanco, Javier G.
Filing Date: December 5, 2003	Attorney Ref. No.: P032 C1
For: EXPANDABLE MEDICAL DELIVERY DEVICE FOR DELIVERY OF BENEFICIAL AGENT	

BRIEF FOR APPELLANT

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMES NOW APPELLANT to present this Brief in support of the appeal of the second and final rejections of Claims 49-51, 53, 56-62, 74-78, and 81-86 in the above-captioned patent application. The Notice of Appeal having been timely filed on 16 September 2005, with a Petition for a one-month extension of time, this Brief is due to be filed on 17 January 2006, with a Petition for a two-month extension of time (16 January 2006 is a federal holiday). 37 C.F.R. §§ 1.7(a), 41.37 (a)(1), (e).

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application or dismissal of this appeal, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to Deposit Account 50-3100.

For the following reasons, Appellant respectfully submits that the final rejection of each of Claims 49-51, 53, 56-62, 74-78, and 81-86 in this application is in error, and therefore respectfully requests reversal of the rejections.

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I. REAL PARTY IN INTEREST

The real party in interest is Conor Medsystems, Inc., a corporation of Delaware.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this appeal.

III. STATUS OF CLAIMS

Claims 49-51, 53, 56-62, 74-78, and 81-86 stand finally rejected in the Office Action dated May 16, 2005. Claims 67-73 have been withdrawn. Claims 1-48, 52, 54, 55, 63-66, 79, and 80 have been cancelled.

IV. STATUS OF AMENDMENTS

All amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Conor Medsystems has designed a novel reservoir-based drug-delivery stent technology with individual drug depots for loading multiple drugs with protective carriers. The Conor stent design incorporated hundreds of drug-delivery reservoirs, filled with a matrix of polymer and a drug. The reservoirs are filled in a plurality of filling and evaporating steps to form independently programmable drug depots.

The Conor depot technology addresses the limitations of current drug-eluting stents. Unique to Conor's technology is the ability to choose drugs and carrier materials which provide independent release kinetics without the limitations of materials suitable for coatings. Conor's

drug-delivery system is also the first system to allow independent drug release kinetics for multiple drugs.

The present application describes expandable medical devices, such as stents, embodying layers of beneficial agents which are used to control release of drugs from the openings or depots in the expandable devices. An expandable medical device 10 includes an expandable device body 12 including and formed by a plurality of struts 18 separated by slots 16, with a plurality of holes or openings 24, 24', 26, 26' formed in the struts (page 10, lines 10-11, and 17-21). Inside the openings, a plurality of layers 50 of beneficial agent 36 are provided, as well as a barrier layer 52 (page 22, line 8 to page 23, line 2) located adjacent a luminal side (*i.e.*, the inside) of the body (page 14, lines 4-15 *et sqq*; page 17, lines 15-16; page 18, lines 4-27). The layers 50 of beneficial agent include a first active agent layer having a first release profile and a second active agent having a second release profile different from the first release profile (*id.*; page 23, line 20 to page 24, line 20).

The active agents are thus exposed to the mural side (outside) of the body (*id.*)

One of the active agents can be an anti-proliferative (page 14, line 18), while another can be an anti-inflammatory (page 14, line 19).

The barrier layer can be formed in the opening (page 22, lines 8-10).

The release profiles can be designed to coordinate with cellular biochemical processes (page 24, lines 3-13).

The two active agent release profiles can have different durations (page 21, lines 1-19).

One of the release profiles can include a programmable burst (page 23, lines 20-26).

The active agents can be the same (*passim*; see, *e.g.*, page 22, lines 8-24) or different (page 24, lines 3-13), and when the same can have different concentrations (page 24, lines 14-20).

The openings can be laser drilled through holes (page 12, lines 22-24).

The body can be a one-piece structure (page 11, line 21 to page 12, line 6; Fig. 1).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The ground of rejection to be reviewed in this appeal is: the rejection of Claims 49-51, 53, 56-62, 74-78, and 81-86 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,656,162, issued to Santini, Jr., *et al.* ("Santini")

VI. ARGUMENTS

A. Introduction

In the Office Action dated May 16, 2005 ("Final Office Action"), beginning at page 2, Claims 49-51, 53, 56-62, 74-78, and 81-86 were rejected under 35 U.S.C. § 102(e), as reciting subject matters that allegedly are anticipated by U.S. Patent No. 6,656,162, issued to *Santini.*

For at least the following reasons, these rejections are in error and should be reversed.

B. Legal Standards

Claim construction begins with the words of the claims. *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971 (Fed. Cir. 1999). Claim language should be interpreted as one reasonably skilled in the art would have interpreted the claim at the time of the patent application date. *Vivid Techs., Inc. v. American Science & Engineering, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999); *Wiener v. NEC Elec., Inc.,* 102 F.3d 534, 539 (Fed. Cir. 1996). Where the claim term has no specialized meaning to persons of skill in the art, the ordinary meaning of the words to those of ordinary skill in the art controls, unless the evidence indicates that the inventor used them differently. *Karlin*, 177 F.3d at 971. Such evidence includes the specification and prosecution history, both of which must be analyzed to determine if the inventor limited or redefined any of those terms. *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-84 (Fed. Cir. 2000); *Vivid Techs.*, 200 F.3d at 804. If claim language is not clear on its face, then intrinsic evidence also should be consulted to resolve the lack of clarity. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001).

Under the doctrine of anticipation, a patent claim is not patentable if the claimed invention lacks novelty. 35 U.S.C. § 102(b); *Karsten Mfg. Comp v. Cleveland Golf*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). Anticipation, a question of fact, focuses on a comparison of the prior art to the subject matter of the claim at issue. *Celeritas Technologies, Ltd. v. Rockwell International Corp.* 150 F.3d 1354, 1361 (Fed. Cir. 1998). "[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas*, 150 F.3d at 1361. A convenient way to consider anticipation is the "four corners" doctrine. The "four corners" doctrine refers to the idea that anticipation requires that each and every limitation of the claimed invention is described either expressly or inherently within the four corners of a single prior art document. *Advanced Display Systems, Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

To anticipate, the prior art reference must also enable one of ordinary skill in the art to make and use the claimed invention, *i.e.*, must be enabling. *Transclean Corp. v. Bridgewood Service, Inc.*, 290 F.3d 1364 (Fed. Cir. 2002) (*citing In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)). The test for a non-enabling disclosure is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art, without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). As the Court of Appeals for the Federal Circuit explained in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003), "a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if that disclosure fails to enable one of skill in the art to reduce the disclosed invention to practice."

C. The rejections of Claims 49-51, 53, 56-62, 74-78, and 81-86 under 35 U.S.C. § 102(e) are in error

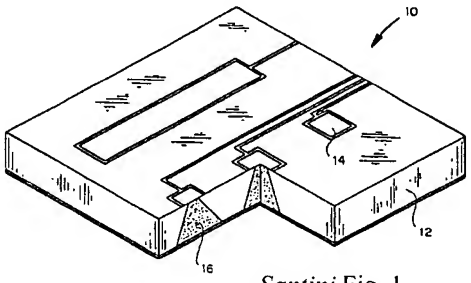
Because each of the twice-rejected, independent claims in this application, to wit Claims 49, 59, and 74, recite different subject matters and are separately patentable, each of the independent claims stands or falls alone. Additionally, the subject matters of each of Claims 50,

51, 53, 56, 62, 75-78, 81, and 84-86 each stands or falls separately. The remaining claims stand or fall with the claim from which each depends.

To simplify consideration of the rejections of the various claims, the sole prior art document relied upon in the Final Office Action, *Santini*, will first be discussed.

(i) Santini

Santini describes microchip devices 10 (Fig. 1, reproduced herein) which, according to *Santini*, can be attached to the inside surface of a stent for drug delivery (see column 14, line 62 to column 15, line 29). Indeed, the three paragraphs bridging columns 14 and 15 in *Santini*, a passage appearing at column 10, line 43 through column 11, line 14, and Figs. 9A, 9B, and 9C appear to include the totality of *Santini*'s disclosure concerning stents.



Santini Fig. 1

The microchip devices of *Santini* include a device of Fig. 2d (also reproduced herein) which has two substrates 510a and 510b, two reservoirs 520a and 520b, a rupturable cap for each reservoir 530a, 530b, and two agents 540a and 540b. The two agent drug delivery device of *Santini* (Fig. 2d) is formed by placing two, single-drug delivery devices on top of one another. *Santini* describes several embodiments, differentiated by the way by which the caps are ruptured: electrically (Figs. 3a-3c); heating (Figs. 4a-4c); mechanically (Figs. 5a-5c); ultrasonically (Figs. 6a, 6b); and dissolution (Figs. 7a-7c). Opposite the cap 530a, the microchip is provided with a sealing backing plate 550.

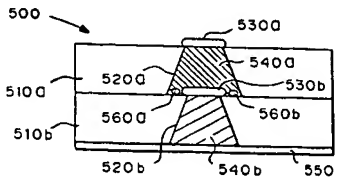
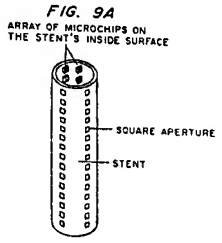
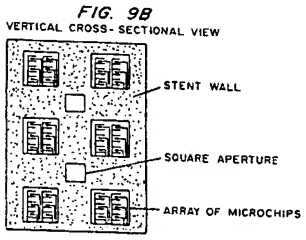


FIG. 2D

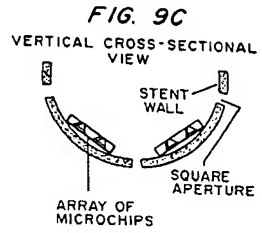
Santini also alleges that the drug reservoirs can be formed as part of the stent itself. More specifically, *Santini* states, with reference to Figs. 9a-9c (reproduced herein):

One embodiment of a microchip device for the release of molecules into a carrier fluid involves integrating one or more drug delivery microchips into/onto a stent, such as a vascular stent. The drug-containing microchips preferably are provided on one or more surfaces of the stent, for example as illustrated in FIGS. 9a-c. The microchip devices can be present in the stent during implantation and stent expansion, or the microchip devices can be attached to the inside of the stent in a separate procedure immediately following stent implantation and expansion. If the microchips are small enough, implantation and attachment of a microchip to a stent can be completed using the same catheter technology used in the implantation of stents. In a preferred embodiment, the microchips of the stent-microchip device are programmed or activated by remote or wireless means to deliver drugs directly from the stent.





One preferred application of the stent-microchip device is the local delivery of anti-restenosis drugs to an artery that has recently undergone an angioplasty procedure. In another embodiment, the stent-microchip devices are used to systemically deliver one or more drugs to a patient via blood flowing through the stent. In another embodiment, stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microchip device, but rather as part of a monolithic stent device. It is understood that both systemic and local delivery of any drug is possible using the microchip technology in combination with stents.



(column 14, line 62 to column 15, line 23).

Santini includes no further explanation of the structure of the stent in the specification; the drawings of Fig. 9 are annotated with: "array of microchips on the stent's inside surface", "square aperture", "stent", "stent wall", and "array of microchips". It therefore appears clear that *Santini*'s disclosure of a stent is limited to only these passages and drawings, with planar microchips mounted to the interior surface of a cylindrical tubular stent having square apertures,

the microchips mounted away from the apertures with the cap of each reservoir directed to the stent's open interior space (see Figs. 9b, 9c, compared to Fig. 1).

(ii) Santini is at least partially non-enabling; the non-enabling portions of Santini cannot anticipate a claimed feature

In the Final Rejection, bridging pages 3-4 under a "Response to Arguments" section, the patent examiner quotes the above section in *Santini*:

> 'stents can be designed and fabricated to have drug reservoirs and caps as part of the stent itself, that is, not as a separate microship [sic: microchip] device, but rather as part of a monolithic stent device. . . .' Said microchip technology includes any of the embodiments shown in Figures 2A-2E.

Appellant vigorously disputes that *Santini*'s microchips can be formed as part of a stent based on this disclosure. To the contrary, *Santini* fails to enable one of ordinary skill in the art to reduce to practice this hypothetical 'monolithic' embodiment, and therefore at least this portion of *Santini* cannot be relied on as a factual basis for anticipation of any element recited in the claims on appeal.

Santini incorporates by reference U.S. Patent No. 6,123,861, also issued to Santini, Jr., *et al.* (" 'Santini '861"), and thus forms a part of *Santini*'s disclosure. More specifically, *Santini* indicates that the "microchip devices can be made, for example, using techniques known in the art, particularly the methods described in U.S. Pat. No. 6,123,861 to Santini et al., which is incorporated by reference". *Santini*, column 12, lines 48-51. While *Santini* goes on in the following lines to allege that the reservoirs of his microchips can be made with 'complex shapes' (col. 12, line 65), the inclusion of *Santini '861* does not cure *Santini*'s inadequate disclosure. *Santini* also glibly alleges that "other fabrication processes, such as plating, casting, or molding, can also be used to make" his microchips. *Santini*, column 12, lines 58-60. *Santini* further states that silicone-on-insulator (SOI) methods can be used to form complex reservoir shapes, such as those illustrated in Figs. 2b, 2c, and 2e. *Santini*, column 12, line 61 to column 13, line 11.

Neither of these alternatives cures the fundamental defect of *Santini*: one of ordinary skill in the art is not enabled by *Santini*'s disclosure to reduce to practice a monolithic stent including *Santini*'s microchip.

Santini appears to acknowledge that the high strain experienced by expandable stents during deployment presents an enormous design problem, when *Santini* indicates that the microchips can be attached to the interior surface of the stent after deployment in the patient's vasculature, *Santini*, column 15, lines 1-8 (reproduced above), as opposed to the microchips already being mounted on the stent when the stent is installed in the patient. Indeed, as explained at great length in this application, all portions of prior expandable stents experienced great strain rates during expansion, including *Santini*'s stents with affixed microchips, and therefore there appears to be only the "fasteners" and "adhesives" (*Santini*, column 13, lines 15-19) to prevent the microchips from just popping off the stent.

Another insurmountable problem with *Santini*'s hypothetical monolithic stent embodiment also arises from the strains all portions of the stent experiences. There would be many problems in how to successfully incorporate *Santini*'s Fig. 2d microchip into a stent, *i.e.*, one can't bend the Fig. 2d structure into a cylindrical stent without delaminating its substrate layers and distorting, cracking, and losing the drugs and caps. While some current stents are formed by first forming a planar, sheetlike structure and then rolling the sheet into a tube, the high hoop (circumferential) stresses thus applied to the stent plainly could not be withstood by the microchip structures formed by the methods described in *Santini*, including those in *Santini '861*. This is yet further evidence that *Santini* does not enable the hypothetical monolithic stent/microchip embodiment. Fundamentally, none of *Santini*'s disclosure enables the skilled artisan to make the monolithic stent/microchip embodiment at the interior surface of a tubular stent, the location disclosed by *Santini* for the microchip.

Santini '861 describes processes of making planar microchip drug delivery devices which could not be used to manufacture a functional drug delivery reservoir in the interior surface of *Santini*'s stent. Beginning at column 7, line 60, *Santini '861* describes "methods of device fabrication", including the steps of "depositing and lithographically patterning a material,

typically an insulating or dielectric material, onto the substrate to serve as an etch mask during reservoir etching." As well understood by those of ordinary skill in the art, lithographically etching requires a planar surface onto which a pattern is burned. Examples of the insulating mask materials, according to *Santini '861*, include "silicone nitride, silicone dioxide, polyimides, silicone-rich nitride, and polycrystalline silicon nitride, deposited onto the lithographically etched substrate using typical semiconductor fabrication processes such as LPCVD and PECVD." Reservoir patterns are then "patterned into the silicon nitride film on one side of the wafer 32/320 by ultraviolet photolithography and either plasma etching or a chemical etch . . .". Reactive ion and ion beam etching are also mentioned. *Santini '861*, column 8, lines 4-51.

Beginning at column 8, line 53, *Santini '861* describes methods of forming the reservoir caps which similarly is not usable for construction of structures in a stent. *Santini '861* describes injecting the cap material via microsyringe, or with an injet printer cartridge, or by spin-coating (lines 56-57), and that these methods are preferable (column 9, lines 8-11). Similar methods are described for forming the "active timed release reservoir caps", including the electrode leads to those caps (*see* column 10, line 11 to column 11, line 2). While perhaps usable on the typical planar substrate of microchip fabrication techniques, these processes are plainly not possible to use on the interior surface of a stent, and no provisions are given to prevent destruction of the structure were a planar substrate to be rolled into a stent.

The two examples in *Santini '861* bridging columns 13 through 19, upon review, are consistent in their inapplicability to the interior surface of a tubular stent, and their failure to provide any disclosure or guidance to the skilled artisan how to keep the microchip's structures intact were it rolled into a tubular stent. Indeed, the first step in both of "obtain[ing] double sided polished, prime grade, (100) oriented silicon wafers" demonstrates that all of the disclosure of *Santini '861* is directed to constructing planar devices, and the resulting microchips could not be compressed or stressed as they would be in the hypothetical stent of *Santini*.

A plain review of this disclosure by the ordinarily skilled artisan would not permit that person to reduce *Santini*'s hypothetical stent device to practice. *Santini '861* fails to discuss any way of forming reservoirs in anything other than the typical planar substrate, and fails to describe

any guidance or measures to be taken to maintain the integrity of the reservoirs and caps were one to roll the substrate into a tube and expose them to high stresses and strains. Thus, the offhanded mention in *Santini* that his microchips might be formed into a monolithic stent is nothing more than a non-enabling prophetic statement that does not permit the skilled artisan to reduce the subject matter to practice. Accordingly, at least this portion of *Santini* is not truly prior art, *Amgen*, and thus cannot anticipate the claimed subject matter for which it is relied.

(iii) The rejection of Claims 49, 57, and 58 is in error

Claim 49 relates to an expandable medical device having a combination of elements including, *inter alia*, an expandable body formed of a plurality of struts, a plurality of openings in the plurality of struts, a plurality of beneficial agent layers formed in the openings, the plurality of beneficial agent layers including a first active agent arranged for delivery according to a first release profile and a second active agent arranged for delivery according to a second release profile, wherein the first and second release profiles are different, and a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.

Santini does not describe an expandable body. *Santini* describes nothing more than a cylindrical tube which he calls a stent.

Santini does not describe a stent with struts. The minimalist stent that *Santini* does describe appears to be a cylindrical tube in which square apertures are formed. The skilled artisan, upon a full reading of *Santini*, would be at odds to take anything else from it's slim disclosure.

Santini doesn't describe struts, and doesn't describe openings formed in struts. While *Santini* describes square holes, they are not formed in struts; they are formed in the stent wall, which is the only structure that *Santini* describes for the overall stent structure.

Santini describes square openings, but opts to leave them open and to mount the microchips 10, 500 to the interior surface of the stent wall. While *Santini* describes the microchips as containing one or more molecules 540a, 540b received in reservoirs 520a, 520b,

respectively, those reservoirs are not formed in struts. Thus, the openings of *Santini*'s device are empty.

Santini describes two molecules that can be released by the microchips, but is otherwise silent about the release rate profiles of those molecules from the microcip, and therefore does not describe active agents having different release profiles as recited in the claimed combination. *Santini* states, at column 4, lines 46-54:

> In one embodiment of the device shown in FIG. 2d, second molecules to be released 540b are first released from reservoir 520b, through or following the disintegration of reservoir cap 530b, into reservoir 520a, wherein the second molecules mix with first molecules to be released 540a before the mixture of molecules is released from reservoir 520a through or following the disintegration of reservoir cap 530a.

While *Santini* goes on in some detail about the 'release system', *Santini* is completely silent about the release profiles of the molecules from their respective reservoirs, and certainly fails to describe different release profiles.

Santini describes the microchips being mounted to the interior surface of the stent wall, with the reservoir cap directed inwardly, *i.e.*, toward the hollow interior lumen of the cylindrical tube which is *Santini*'s stent, which is exactly opposite the orientation recited in the claimed combination. *Santini* describes the desirability of releasing molecules into the bloodstream (see col. 15, lines 12-17), and therefore understandably points his microchips at the interior of the stent, rather than including a barrier layer adjacent a luminal side (that is, the inside of the claimed cylindrical expandable body) which retards delivery of agents to the luminal side of the body. Thus, assuming *arguendo* that *Santini*'s substrate 12, 510a, 510b could be considered to be a barrier layer, the substrate and reservoirs of *Santini*'s device are simply pointed the wrong way.

For at least the foregoing reasons, Appellant respectfully submits that *Santini* fails to describe each and every element exactly as recited in the combinations of Claims 49, 57, and 58.

(iv) The rejection of Claim 50 is in error

Claim 50 recites that, in the combination of Claim 49, the first and second active agents are arranged to be delivered to a mural side of the device body. The mural side is the side facing the artery wall when the stent is placed therein, *i.e.*, the outside of the stent. *Santini*'s microchip's reservoirs are plainly directed to the luminal side of the stent, *i.e.*, to the inside of the stent. Thus, even if the subject matter of Claim 49, from which Claim 50 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 50, and is thus separately patentable.

(v) The rejection of Claim 51 is in error

Claim 51 recites that, in the combination of Claim 50, the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory. *Santini* fails to disclose a stent including the full combination of elements recited in Claim 51. Instead, *Santini* indicates that an intravenous (IV) embodiment of his invention, such as that illustrated in Figs. 8a-8c, can include a microchip including "anti-inflammatory agents" (column 9, lines 44), while a stent embodiment of his invention can include a microchip mounted to the interior surface of the stent (Figs. 9a-9c) including "anti-restenosis compounds" (column 9, line 60). Nowhere does *Santini* disclose to the skilled artisan that a stent has one reservoir including an anti-proliferative and another reservoir including an anti-inflammatory or the direction that these should be delivered from the stent. Thus, even if the subject matter of Claim 50, from which Claim 51 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 51, and is thus separately patentable.

(vi) The rejection of Claim 53 is in error

Claim 53 recites that, in the combination of Claim 50, the barrier layer is formed within the openings. *Santini* describes both rupturable caps 530a, b, on the luminal side of the reservoirs, and an impermeable and permanent substrate 550, on the mural side of the reservoirs. Both the caps and substrate are not formed in the reservoir openings; rather, the caps are plainly

formed outside of *Santini*'s reservoir's openings, and the substrate is similarly formed outside the lower (in Fig. 2d) reservoir. Thus, even if the subject matter of Claim 50, from which Claim 53 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 53, and is thus separately patentable.

(vii) The rejection of Claim 56 is in error

Claim 56 recites that, in the combination of Claim 49, the first and second release profiles are designed to coordinate with cellular biochemical processes. *Santini* describes nothing about the release profiles of the molecules of his microchips; at most, *Santini* may discuss the overall release time, but fails to describe any of the characteristics of the release profiles. Thus, because *Santini* fails to provide any details concerning his molecules' release profiles, *Santini* fails to disclose release profiles that relate in any way to cellular biochemical processes. Thus, even if the subject matter of Claim 49, from which Claim 56 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 56, and is thus separately patentable.

(viii) The rejection of Claim 84 is in error

Claim 84 recites that, in the combination of Claim 49, the plurality of openings are laser drilled holes and the device body is a one piece cylindrical structure. As discussed at great length above, *Santini* describes forming his microchips using traditional microchips fabrication techniques, which involve coating, masking, etching, and depositing materials to build up layers on a silicone wafer. Nowhere does *Santini* disclose or describe laser drilling to form any portion of his devices. As also discussed at great length above, *Santini* fails to disclose a single piece device body, but instead describes attaching microchips to the interior surface of a largely featureless stent; *Santini*'s bald mention of a monolithic stent/microchip device is non-enabling, and therefore cannot be an anticipatory disclosure. Thus, even if the subject matter of Claim 49, from which Claim 84 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 84 and is thus separately patentable.

(ix) The rejection of Claims 59-61 in error

Claim 59 relates to an expandable medical device having a combination of elements including, *inter alia*, an expandable body formed of a plurality of struts, a plurality of openings in the plurality of struts, and a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent layer arranged for delivery primarily to a first side of the device body and a second active agent layer arranged for delivery to the first side of the device body.

Santini does not describe an expandable body. *Santini* describes nothing more than a cylindrical tube which he calls a stent.

Santini does not describe a stent with struts. The minimalist stent that *Santini* does describe appears to be a cylindrical tube in which square apertures are formed. The skilled artisan, upon a full reading of *Santini*, would be at odds to take anything else from it's slim disclosure.

Santini doesn't describe struts, and doesn't describe openings formed in struts. While *Santini* describes square holes, they are not formed in struts; they are formed in the stent wall, which is the only structure that *Santini* describes for the overall stent structure.

Santini describes square openings, but opts to leave them open and to mount the microchips 10, 500 to the interior surface of the stent wall. While *Santini* describes the microchips as containing one or more molecules 540a, 540b received in reservoirs 520a, 520b, respectively, those reservoirs are not formed in struts. Thus, the openings of *Santini*'s device are empty.

For at least the foregoing reasons, Appellant respectfully submits that *Santini* fails to describe each and every element exactly as recited in the combinations of Claims 59-61.

(x) The rejection of Claim 62 is in error

Claim 62 recites that, in the combination of Claim 59, the first and second active agent layers include the same active agent in different concentrations. While *Santini* briefly alleges

that the molecules 540a, 540b can be the same or different (column 4, lines 38-40), *Santini* is entirely silent on the concentrations of the molecules in the reservoirs. Thus, even if the subject matter of Claim 59, from which Claim 62 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 62 and is thus separately patentable.

(xi) The rejection of Claim 85 is in error

Claim 85 recites that, in the combination of Claim 59, the plurality of openings are laser drilled holes and the device body is a one piece cylindrical structure. As discussed at great length above, *Santini* describes forming his microchips using traditional microchips fabrication techniques, which involve coating, masking, etching, and depositing materials to build up layers on a silicone wafer. Nowhere does *Santini* disclose or describe laser drilling to form any portion of his devices. As also discussed at great length above, *Santini* fails to disclose a single piece device body, but instead describes attaching microchips to the interior surface of a largely featureless stent; *Santini*'s bald mention of a monolithic stent/microchip device is non-enabling, and therefore cannot be an anticipatory disclosure. Thus, even if the subject matter of Claim 59, from which Claim 85 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 85 and is thus separately patentable.

(xii) The rejection of Claims 74, 82, and 83 is in error

Claim 74 relates to an expandable medical device having a combination of elements including, *inter alia*, an expandable body formed of a plurality of struts, a plurality of openings in the plurality of struts, a first active agent contained in the plurality of openings and arranged for delivery according to a first release profile, and a second active agent contained in the plurality of openings and arranged for delivery according to a second release profile, wherein the first and second release profiles are different, and wherein the first and second active agents are arranged to be delivered to a first side of the device body.

Santini does not describe an expandable body. *Santini* describes nothing more than a cylindrical tube which he calls a stent.

Santini does not describe a stent with struts. The minimalist stent that *Santini* does describe appears to be a cylindrical tube in which square apertures are formed. The skilled artisan, upon a full reading of *Santini*, would be at odds to take anything else from it's slim disclosure.

Santini doesn't describe struts, and doesn't describe openings formed in struts. While *Santini* describes square holes, they are not formed in struts; they are formed in the stent wall, which is the only structure that *Santini* describes for the overall stent structure.

Santini describes square openings, but opts to leave them open and to mount the microchips 10, 500 to the interior surface of the stent wall. While *Santini* describes the microchips as containing one or more molecules 540a, 540b received in reservoirs 520a, 520b, respectively, those reservoirs are not formed in struts. Thus, the openings of *Santini*'s device are empty.

Santini describes two molecules that can be released by the microchips, but is otherwise silent about the release rate profiles of those molecules from the microchip, and therefore does not describe active agents having different release profiles as recited in the claimed combination. *Santini* states, at column 4, lines 46-54:

> In one embodiment of the device shown in FIG. 2d, second molecules to be released 540b are first released from reservoir 520b, through or following the disintegration of reservoir cap 530b, into reservoir 520a, wherein the second molecules mix with first molecules to be released 540a before the mixture of molecules is released from reservoir 520a through or following the disintegration of reservoir cap 530a.

While *Santini* goes on in some detail about the 'release system', *Santini* is completely silent about the release profiles of the molecules from their respective reservoirs, and certainly fails to describe different release profiles.

For at least the foregoing reasons, Appellant respectfully submits that *Santini* fails to describe each and every element exactly as recited in the combinations of Claims 74, 82, and 83.

(xiii) The rejection of Claim 75 is in error

Claim 75 recites that, in the combination of Claim 74, the first and second active agents are arranged to be delivered to a mural side of the device body. The mural side is the side facing the artery wall when the stent is placed therein, *i.e.*, the outside of the stent. *Santini*'s microchip's reservoirs are plainly directed to the luminal side of the stent, *i.e.*, to the inside of the stent. Thus, even if the subject matter of Claim 74, from which Claim 75 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 75, and is thus separately patentable.

(xiv) The rejection of Claim 76 is in error

Claim 76 recites that, in the combination of Claim 75, the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory. *Santini* fails to disclose a stent including the full combination of elements recited in Claim 51. Instead, *Santini* indicates that an intravenous (IV) embodiment of his invention, such as that illustrated in Figs. 8a-8c, can include a microchip including "anti-inflammatory agents" (column 9, lines 44), while a stent embodiment of his invention can include a microchip mounted to the interior surface of the stent (Figs. 9a-9c) including "anti-restenosis compounds" (column 9, line 60). Nowhere does *Santini* disclose to the skilled artisan that a stent has one reservoir including an anti-proliferative and another reservoir including an anti-inflammatory. Thus, even if the subject matter of Claim 75, from which Claim 76 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 76, and is thus separately patentable.

(xv) The rejection of Claim 77 is in error

Claim 77 recites that, in the combination of Claim 75, the device further includes a barrier layer adjacent a luminal side which retards delivery of agents to the luminal side of the

body. *Santini* describes the microchips being mounted to the interior surface of the stent wall, with the reservoir cap directed inwardly, *i.e.*, toward the hollow interior lumen of the cylindrical tube which is *Santini*'s stent, which is exactly opposite the orientation recited in the claimed combination. *Santini* describes the desirability of releasing molecules into the bloodstream (see col. 15, lines 12-17), and therefore understandably points his microchips at the interior of the stent, rather than including a barrier layer adjacent a luminal side (that is, the inside of the claimed cylindrical expandable body) which retards delivery of agents to the luminal side of the body. Thus, assuming *arguendo* that *Santini*'s substrate 12, 510a, 510b could be considered to be a barrier layer, the substrate and reservoirs of *Santini*'s device are simply pointed the wrong way. Thus, even if the subject matter of Claim 75, from which Claim 77 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 77, and is thus separately patentable.

(xvi) The rejection of Claim 78 is in error

Claim 78 recites that, in the combination of Claim 77, the barrier layer is formed within the openings. *Santini* describes both rupturable caps 530a, b, on the luminal side of the reservoirs, and an impermeable and permanent substrate 550, on the mural side of the reservoirs. Both the caps and substrate are not formed in the reservoir openings; rather, the caps are plainly formed outside of *Santini*'s reservoir's openings, and the substrate is similarly formed outside the lower (in Fig. 2d) reservoir. Thus, even if the subject matter of Claim 77, from which Claim 78 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 77, and is thus separately patentable.

(xvii) The rejection of Claim 81 is in error

Claim 81 recites that, in the combination of Claim 74, the first and second release profiles are designed to coordinate with cellular biochemical processes. *Santini* describes nothing about the release profiles of the molecules of his microchips; at most, *Santini* may discuss the overall release time, but fails to describe any of the characteristics of the release profiles. Thus, because

Santini fails to provide any details concerning his molecules' release profiles, *Santini* fails to disclose release profiles that relate in any way to cellular biochemical processes. Thus, even if the subject matter of Claim 74, from which Claim 81 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 81, and is thus separately patentable.

(xviii) The rejection of Claim 86 is in error

Claim 86 recites that, in the combination of Claim 74, the plurality of openings are laser drilled holes and the device body is a one piece cylindrical structure. As discussed at great length above, *Santini* describes forming his microchips using traditional microchips fabrication techniques, which involve coating, masking, etching, and depositing materials to build up layers on a silicone wafer. Nowhere does *Santini* disclose or describe laser drilling to form any portion of his devices. As also discussed at great length above, *Santini* fails to disclose a single piece device body, but instead describes attaching microchips to the interior surface of a largely featureless stent; *Santini*'s bald mention of a monolithic stent/microchip device is non-enabling, and therefore cannot be an anticipatory disclosure. Thus, even if the subject matter of Claim 74, from which Claim 86 depends, is found to be not patentable to Appellant, *Santini* still fails to identically disclose the subject matter of Claim 86 and is thus separately patentable.

(xix) Conclusion

For at least the foregoing reasons, Appellant respectfully submits that the subject matters of Claims 49-51, 53, 56-62, 74-78, and 81-86 are not anticipated by *Santini*, and are therefore not unpatentable under 35 U.S.C. § 102.

D. Claims 49-51, 53, 56-62, 74-78, and 81-86 are patentable

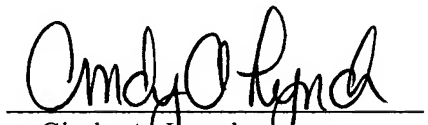
For at least the reasons presented herein, each of the subject matters of Claims 49-51, 53, 56-62, 74-78, and 81-86, taken as a whole, is patentable over *Santini*. Accordingly, the rejection of each of Claims 49-51, 53, 56-62, 74-78, and 81-86 under section 102(e) is reversible error.

IX. CONCLUSION

For at least the foregoing reasons, Appellant respectfully submits that the rejections of the claims in this patent application are in error, and therefore respectfully requests reversal thereof.

Respectfully submitted,

John F. Shanley *et al.*

By: 
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Date: January 12, 2006

CLAIMS APPENDIX

49. An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;

a plurality of openings in the plurality of struts; and

a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent arranged for delivery according to a first release profile and a second active agent arranged for delivery according to a second release profile, wherein the first and second release profiles are different; and

a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.

50. The device of Claim 49, wherein the first and second active agents are arranged to be delivered to a mural side of the device body.

51. The device of Claim 50, wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory.

53. The device of Claim 50, wherein the barrier layer is formed within the openings.

56. The device of Claim 49, wherein the first and second release profiles are designed to coordinate with cellular biochemical processes.

57. The device of Claim 49, wherein the first and second release profiles are of different duration.

58. The device of Claim 49, wherein the first release profile includes programmable bursts.

59. An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;

a plurality of openings in the plurality of struts; and

a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent layer arranged for delivery primarily to a first side of the device body and a second active agent layer arranged for delivery to a the first side of the device body.

60. The device of Claim 59, wherein the first and second active agent layers include different active agents.

61. The device of Claim 59, wherein the first and second active agent layers include the same active agent.

62. The device of Claim 59, wherein the first and second active agent layers include the same active agent in different concentrations.

74. An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;

a plurality of openings in the plurality of struts; and

a first active agent contained in the plurality of openings and arranged for delivery according to a first release profile; and

a second active agent contained in the plurality of openings and arranged for delivery according to a second release profile, wherein the first and second release profiles are different; and

wherein the first and second active agents are arranged to be delivered to a first side of the device body.

75. The device of Claim 74, wherein the first and second active agents are arranged to be delivered to a mural side of the device body.

76. The device of Claim 75, wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory.

77. The device of Claim 75, further comprising a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.

78. The device of Claim 77, wherein the barrier layer is formed within the openings.

81. The device of Claim 74, wherein the first and second release profiles are designed to coordinate with cellular biochemical processes.

82. The device of Claim 74, wherein the first and second release profiles are of different duration.

83. The device of Claim 74, wherein the first release profile includes programmable bursts.

84. The device of Claim 49, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

85. The device of Claim 59, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

86. The device of Claim 74, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

EVIDENCE APPENDIX

No additional evidence is cited in this Brief.

RELATED PROCEEDINGS APPENDIX

There are no proceedings related to this appeal.